United States Department of Agriculture
Center for Veterinary Biologics

Standard Operating Policy/Procedure

Inspection and Compliance Correspondence
(LSRTIS, Mail Log Procedures)

Date: **April 13, 2018**

Number: ICSOP0045.02

Supersedes: ICSOP0045.01, September 1, 2016

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Entered into CVB Quality Management System
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1. Purpose

Licensees and permittees submit information to the Center for Veterinary Biologics-Inspection and Compliance (CVB-IC) for review, and in many cases, authorization for certain functions. Official requests and responses must be in writing. The process used to receive and route the individual submissions is a controlled, yet flexible process.

This documents outlines the general information regarding the receipt, review, and routing of initial submissions, generated either internally or externally. See **ICSOP0042**, *General Inspection and Compliance Correspondence Guidance*, for additional Correspondence Guidance.

2. Definitions

2.1 Record

A submission generated by a regulated, unregulated entity, or CVB-IC in the course of accomplishing the CVB Mission. The submission becomes a record in LSRTIS that is reviewed and processed by CVB.

2.2 NCAH Portal

An external-facing application which enables web-based electronic submissions and responses between biologics firms and the CVB.

2.3 LSRTIS

This database system is the information management system used by the CVB for various regulatory functions.

3. Responsibilities

3.1 Specialist

May initiate correspondence or do a preliminary review of incoming correspondence. Also, signs outgoing correspondence.

3.2 Biologics Compliance Assistant (BCA)

Performs a primary review of correspondence, finalizes all outgoing documents to send to specified recipients.

3.3 Section Leader

Performs a review of regulations to outgoing correspondence, provides consistency in policy, and ensures documents are accurate.

3.4 System Administrators (LSRTIS)

Provide support to employees for system functions within LSRTIS.

4. Procedures

4.1 Overview

See workflow diagrams (**Appendix I**) for general routing of documents from the NCAH Portal and Compliance Correspondence initiated from the CVB.

4.2 Initiation of Correspondence

Incoming correspondence (except correspondence that is received with APHIS Form 2007s and 2008s) must be entered into the Mail Log portion of LSRTIS. NOTE: Export Certification (Certificates of Licensing and Inspection and Export Certificates) are not within the scope of this standard operating procedure.

4.2.1 NCAH Portal, recommended method for submission of records from firms.

4.2.1.1 The NCAH portal enabled manufacturers have the ability to submit records through the NCAH Portal.

4.2.1.2 Submission via the NCAH Portal is considered an authentic submission and does not require any additional electronic signatures.

4.2.1.3 The record should include an attachment. This is usually the firm's letter requesting an authorization or providing information. Title 9, *Code of Federal Regulations*, part 116.5, notifications are exceptions.

4.2.1.4 Submissions usually go directly to the CVB, Mail Log, IC Inbox Pool Queue. See **Section 4.3.1** for routing guidance.

4.2.2. Submissions via mail (hard copy of documents from the firm). See **ICWI0910**, *Mail Receipt, Process, and Distribution for CVB – IC Hard Copy Submissions*, on processes for receiving incoming mail.

4.2.3. Internally Generated Documents. Specific procedures are needed for various submissions types or submission subtypes that are created by employees at the CVB-IC. The following are different submission types that may be internally generated. Current templates are to be used. See the **Inspection and Compliance Manual** located on the CVB Quality Management SharePoint site for the current template. (Documents not on current templates will be returned to the author for revision.)

4.2.3.1 Inspection Reports. See **ICWI0215**, *Routing of Inspection Reports – for Specialist,* for guidance on initiating and review of the inspection report and any additional information contained.

4.2.3.2 Regulatory Letters. See **ICSOP0105**, *Compliance Policy for Issuing Regulatory Actions*, and **ICWI0618**, *Work Flow for Initiating a Regulatory Action or Regulatory Correspondence Using the Mail Log System and Portal,* for guidance on initiating and review of compliance letters.

4.2.3.3 AIR (Administrative Inspection Review) Processing Documents. See **ICWI0242**, *Preparation of Administrative Inspection Reviews,* for guidance on initiating and review of AIR documents.

4.2.3.4 CVB Employee Assignment Changes. See **ICTEM0015**, *Personnel Changes – Letter to Firm,* for the template.

4.3 Routing of Mail Log Items

Correspondence may be routed to different Mail Log activities, based upon the submission type or submission subtype of the Mail Log document, or who initiated the record. For instance, the Biologics Specialist may initiate an Inspection Report record or Regulatory based letter, see the work instructions listed above in **Section 4.2.3**. Biologics manufacturer may prepare a record and submit it (hard copy) through the U.S. Postal or Courier Mail system or through the NCAH Portal.

4.3.1 IC Inbox. This is a pool queue in which a Mail Log item does not have a CVB employee currently assigned to it. The BCAs typically assign Mail Log items to themselves from this queue. See **ICWI0073,** *IC Inbox Queue*, as to guidance for this queue. Submissions through the NCAH Portal are sent to this tab in the Mail Log.

4.3.2 Facility Document Pool Queue. This is a pool queue, for facility documents only, in which a Mail Log item does not have a CVB employee currently assigned. The BCAs typically assign Mail Log items to themselves from this queue. Mail log items from the NCAH Portal, with the submission type of Facility Document will go here automatically.

4.3.3 Review (BCA). This is a main activity queue that is primarily assigned to the BCAs. This activity is an initial review of the document to determine priority of the document as to whom it will be assigned to, and also a check for consistency and accuracy of the information entered. See **ICWI0071**, *BCA Entry and Review of Incoming Correspondence*, as to guidance for this queue.

4.3.4 Review (Specialist). This is a main activity queue in which the Biologics Specialist does a review of compliance issues or firm requests. They may also determine if a response is needed or not. Below are four typical response types:

4.3.4.1 No Response is needed. These are usually submissions by the manufacturer that are submitted for information only. See **ICWI0236**, *Mail Log Work Flow for Correspondence for Inspection and Compliance Biologics Specialist Review,* for processing of Mail Log items. This may include the firm's responses to inspection findings as documented in the inspection report.

4.3.4.2 Response in the form of a General Correspondence. See **ICWI0236** for processing of Mail Log items.

Follow the templates for responses in either:
ICTEM0001, *CVB Letter*, or
ICTEM0016, *Process Deviation*, templates.

4.3.4.3 Response in the form of a Compliance Correspondence. See **ICSOP0105** and **ICWI0618** for Compliance Policy and Regulatory Actions.

Follow the templates for responses in one of the following:
ICTEM0004, *CVB Certified Letter*;
ICTEM0005, *Regulatory – Letter of Advice*;
ICTEM0007, *Regulatory – Hold Release – Reference*;
ICTEM0008, *Regulatory – Infraction Notice*;
ICTEM0022, *Regulatory – Voluntary Stop*;
ICTEM0024, *Regulatory – Warning Letter*;
ICTEM0037, *Regulatory – APHIS Mandated*, templates.

4.3.4.4 Response of an Inspection Report. See **ICWI0215**, *Routing of Inspection Reports – for Specialist*.

4.3.4.5 Response to the Administrative Inspection Review (AIR) packet. See I**CWI0241**, *Processing Incoming Administrative Inspection Review (AIR) Documents by CVB*.

4.3.5 Section Leader Review (IC). This is an approval step that is assigned to all IC Section Leaders and a few ad hoc employees, like the Facilities Manager and Investigation Manager, or those acting for them. All compliance letters should be reviewed in this activity, as well as all Inspection Reports. Other correspondence that may need concurrence or further review should be reviewed in this activity as well. See the corresponding IC work instructions as listed above for specific Section Leader review.

4.3.6 Finalization. The BCA formats the document, reviews information for consistency and clarity.

4.3.6.1 Hard copy documents are returned to the firms in accordance with **ICWI0111**, *CVB-IC Mail/Filing*.

4.3.6.2 Documents returned via the NCAH Portal must also be reviewed for consistencies in Mail Log entries of secondary information, such as tags, functional linkages, and correct attachment types used. See **ICWI0072**, *Biologics Compliance Assistant (BCA) Finalization of Correspondence*, for details.

4.3.7 Sign Correspondence. This action is the author signing the correspondence electronically or hard copy.

4.3.7.1 Hard copy correspondence also needs to be moved within the Mail Log to perform this action. The document is just simply signed, and the document is routed to the Section Leader for reviewing the final document, see **Section 4.3.8**.

4.3.7.2 Electronic correspondence that is in Adobe pdf format should be digitally signed with the following guidance:

[redacted]

Ignore the section in reference to the experimental label image.

4.3.8 Section Leader Final Authorization. This step is the final check for consistency and content review by the IC Section Leaders. This occurs after electronic or hard copy correspondence has been signed by the author.

4.3.8.1 Review of the signed electronic document including the following:

- The content of the letter meets the policy of CVB-IC,
- The letter is digitally signed with the USDA Logo added,
- The attachment type of the document matches the intended document (i.e., Compliance Correspondence),

- All versions of the draft documents are the same document type.
- The last item the Section Leader needs to determine is if the Mail Log item may go back to the NCAH Portal or should be suppressed from the Portal (in these cases, a hard copy document must be printed).

4.3.9 Records Management. After a document is signed, the Mail Log item should be moved the Records Management Activity, if correspondence is attached and a yellow copy is filed. If no outgoing correspondence is attached or no yellow copy is filed, the Mail Log item may be moved to Workflow Completed - No Records Management Activity.

4.4 Records Management Procedures

Depending on the steps from **4.3.4**, dictates what role the Records Management team does with the Mail Log item. For details on quality assurance steps, see the correspondence guidance for PIMS Quality Assurance steps.

4.4.1 Records Management (RM) – Hard Copy Documents. This step entails filing the hard copy incoming document and/or response, if not received from the NCAH Portal.

4.4.2 Records Management (RM) – Portal Enabled. This step may entail performing a quality assurance review of the outgoing Mail Log item if it is going back to the manufacturer through the NCAH Portal. See **PIMSWI0045**, *Records Management, Quality Assurance of Inspection and Compliance Outgoing Correspondence via NCAH Portal*.

4.4.3 Workflow Completed – No Records Management. This activity is chosen when there is a Mail Log item that has nothing to file or goes back to the manufacturers, either hard copy or through the NCAH Portal.

4.5 System Functions/Releases to NCAH Portal

See the System Administrators for LSRTIS for functionality in which the normal process needs to be halted or updated.

4.5.1 Daily Email to the firms.

4.5.1.1 Included Items:

- Inspection and Compliance – Correspondence
  Serial release notifications are <u>not</u> included – these will remain in their individual emails at 11 a.m. and 3 p.m., Central time.

- Policy Evaluation, and Licensing – Correspondence, Labels

- CVB Laboratory – Information of Serials put on Test, once an APHIS Form 2008 has been received by the firm.

- Sample Processing – Samples received, with the corresponding Sample Code assigned.

4.5.1.2 How to update this Email Address:

See instructions within **ICWI0239**, *Process for Email Address for Electronic Notification of Serial Release*.

4.5.2 Documents/Information Released to NCAH Portal

The Liaison/Alternate Liaison, Quality Review role at the firm may search on IC Correspondence. Updates to the NCAH Portal are sent at 11 a.m. and 3 p.m., Central time. Updates include a status change with the applicable CVB Response or CVB Initiated Correspondence.

Status Changes for the Firm (within the NCAH Portal):

- **Submitted** – Submission been sent from the NCAH Portal to the CVB Mail Log and is an Active Mail Log item.

- **Awaiting Update from Submitter** – Upon request by the firm to CVB (either by email or phone call to the Biologics Specialist or other IC employee).

- **Complete** – The Mail activity has been completed for the Mail Log with one of the following outcomes: 1) *CVB Response* – the Outgoing Correspondence Files (Outgoing General Correspondence, Outgoing Compliance Correspondence, Outgoing Enclosure document types) will be displayed within the Portal. 2) *No Outgoing Correspondence* – The submission does not require an immediate response from the CVB-IC. The incoming document has been received and filed. 3) *CVB Initiated Correspondence* – Any correspondence that initiated at the CVB, such as Outgoing Inspection Report. 4) *Response is linked to a different Mail Log Item* – CVB may link multiple Mail Logs together, where only one submission will contain the CVB Response (Functionally linked Mail Log items). The Mail Log item that does not have the outgoing correspondence will have a CVB Response of "See ML xxxxxx for CVB Response to this Submission".

  All "open" submissions remain in the NCAH Portal until they are completed. Completed submissions are available for 60 days after their last action date. Firms are required to download CVB responses to their own system.

5. Summary of Revisions

Version .02

- Updated flow charts
- Added Facility Document Pool Queue (Section 4.3.2)

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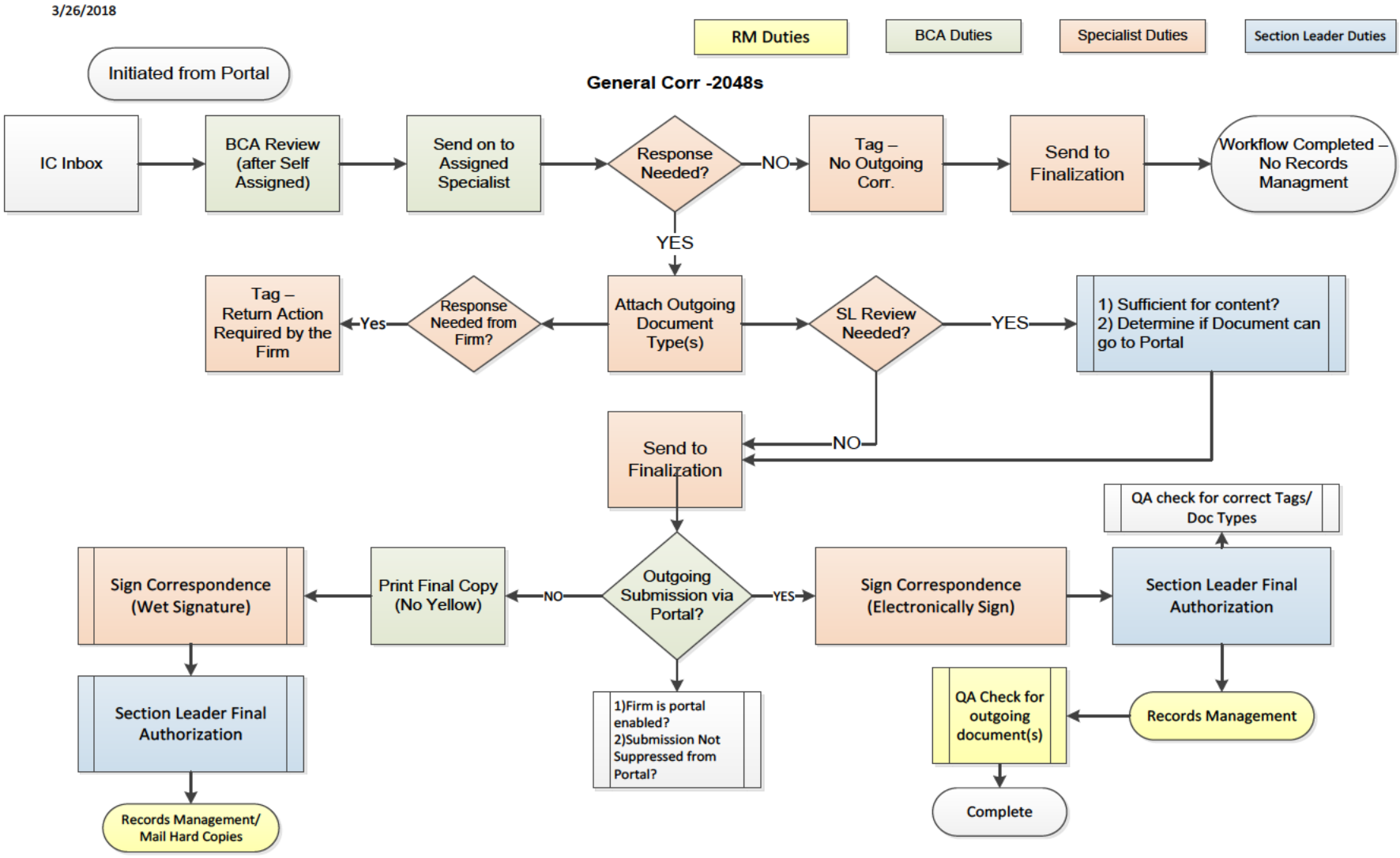
Appendix I



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